Summary of Safety and Effectiveness Information **Special 510(k): Device modification** **Premarket Notification, Section 510(k)**	***Tornier Cement Restrictor*** **Tornier S.A.**

K001932

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

JUL 2 0 2000

1) Device name

Trade name: ***Tornier Cement Restrictor***

Common name: Canal Plug, Cement Restrictor

Classification name: Cement Obturator

2) Established name & Registration number

Name: Tornier S.A.

Number: 9610667

3) Classification

Cement Obturator, as categorized under 21 CFR, §878.3300.

§ 878.3300 Surgical mesh. (a) Identification. Surgical mesh is a metallic or polymeric screen intended to be implanted to reinforce soft tissue or bone where weakness exists. Examples of surgical mesh are metallic and polymeric mesh for hernia repair, and acetabular and cement restrictor mesh used during orthopedic surgery. (b) Classification. Class II.

Device class: Class II

Classification panel: Orthopedic

Product code: 87 LZN

4) Special control

Not applicable to this device.

5) Device background

The present device modification submission concerns the addition of one size to the previous range.

The *Tornier Cement Restrictor* is already legally marketed for one size (24 mm diameter) as a Cement Obturator (K973453). This device exists also in an other size (38 mm). This additional size allows to fit all diaphyseal diameters, while keeping in the same indications for use already covered by the previous 510(k) clearance.

6) Labeling

IMPORTANT : The implantation of a joint prosthesis requires a knowledge of anatomy, biomechanics and reconstructive surgery of the locomotive apparatus and may be performed only by a qualified surgeon. The surgeon must operate in accordance with current information on the state of scientific progress and the art of surgery.

Caution: The Federal (United States) Law restricts this device to sale, distribution and use by or on the order of a physician.

Warning and caution: Never re-use an implant, even if it is in perfect condition. Never resterilize an implant.

Known contraindication to date: Acute or chronic infectious diseases of any aetiology and localization, unsuitable or insufficient bone support, bone immaturity, known allergy to the material.

Side effect and possible complication: Infection. Some complications and side-effects may stem from a lack of awareness of the precautions for use mentioned below.

Pre-operatively: The surgeon must be fully conversant with all the aspects of the surgical technique and know the indications and contra-indications of this type of implant. The surgeon must have acquainted himself before the operation with the specific operative technique of the product which is available from the manufacturer.

As part of the pre-operative examination, the surgeon must check that no biological, biomechanical or other factors are present that will affect the correct conduct of the operation and the postoperative period. Check that the implant has not suffered any deterioration.

Intra-operatively: The functional surfaces of the implants must not suffer any damage, shock, abrasion or other deterioration.

Post-operatively: Patients must be informed by the surgeon of the precautions they must take in everyday life to guarantee the maximum implant service life.

7) Equivalent / Predicate device

Tornier Cement Restrictor, Tornier S.A., K973453.
Allo Pro Cement Obturator. Allo Pro, GmbH., K830949.

8) Device description

Comparison with the cleared device: The shape of the 38 mm *Tornier Cement Restrictor* is similar to the 24 mm diameter one. The central plug of this new device is 2 mm larger than the central plug of the 24 mm diameter Cement restrictor. The petals are also 6 mm longer.

Description: The *Tornier Cement Restrictor* is a diaphyseal plug for orthopedic use. It is designed to occlude the medullary cavity before the introduction of acrylic cement. *The Tornier Cement Restrictor* is used to prevent the cement progression in the diaphysis and therefore facilitate the cement pressurization during the introduction of the implant. Its flexible retractable mechanism makes it adaptable to different diameters of medullary canal to be occluded. It is essential to implant the Tornier Cement Restrictor with the Tornier instrumentation specifically designed for this purpose.

Before cementing the stem, the *Tornier Cement Restrictor* is inserted into the bone shaft. Two sizes are avaible, the smaller is indicated for diaphyseal diameters from 6 to 15 mm and the bigger is indicated for 9 mm diameter and above. Within a range of two sizes, its design allows to fit all diaphyseal diameters.

Graduated inserter: The Cement Restrictor is inserted with the help of a graduated insertor. Proper insertion depth of the *Tornier Cement Restrictor* is calculated by adding 10 mm to the stem length. The inserter is affixed to the plug and then passed down into the canal to the predetermined depth. Once the plug is positioned into the shaft, the inserter is removed, and the cement is injected.

Materials: The *Tornier cement restrictor* is made of ultra high molecular weight polyethylene (UHMWPE) described by ISO standard 5834-2. This material is universally known as a standard medical grade form of polyethylene.

Instrumentation: The graduated inserter instrument required to properly place the *Tornier Cement Restrictor* is supplied in "clean only" condition and must be cleaned and sterilized prior to each use. Remove all labels and packaging materials before cleaning and sterilization. Wash the inserter thoroughly before each use, re-use and sterilization.

Voluntary standards: Various voluntary performance standards are used. They include Tornier S.A. Standard Operating Procedures (SOP), vendors certifications and qualification procedures, Quality system Regulations (QSR), ISO 9001 & EN 46001 specifications and European CE marking.

Design control activities:
Risk analysis method: The risk analysis is carried out during the design of a specific product, a new product or a modified product. The process of risk analysis is defined in a SOP. This is a summary of the method:

1. Identification of critical features
2. Identification of potential hazards coming from these characteristics
3. Identification of harms
4. Risk analysis: estimation of the level of the risk relating to each identified hazard.

The estimation takes into account the evaluation of the frequency and gravity degree of the harm. The combination of the two parameters gives the degree of acceptability of the risk.

The process of risk analysis uses some elements of the NF EN 1441 standard.

Identification of hazards and validation activities: Based on this method, the device modification (additional size) allows identifying different kinds of hazards:

- Hazards common to both sizes of the Cement Restrictor:
  - Risk of device moving while cementing inducing difficulties to remove the implant in case of revision.
    Action: a biomechanical comparison analysis with other legally marketed devices has been performed on the smaller size considered as the worse case. It has demonstrated the same resistance to displacement as the Allo Pro plug when directly loaded in the simulated bone shaft.
  - Risk of important penetration of the cement through the restrictor inducing difficulties to remove the implant in case of revision.
    Action: a biomechanical comparison analysis with other legally marketed devices has been performed on the smaller size considered as the worse case. It has demonstrated the lower penetration of the cement for the *Tornier Cement Restrictor* when compared to the Allo Pro plug tested in the same configuration.
- Specific hazard to the additional 38 mm diameter size:
  - Risk of utilization of the new size of restrictor in a diaphyseal diameter smaller than the diameter of the plug center inducing failure of the bone medullar canal.
    Action: complement of Instructions for use describing the limited diameters adapted to each device size.

The actions implemented after the risk analysis allow to diminish identified risks and to make them acceptable regarding the patient's benefit.

Storage and handling: The prosthetic components must be handled and stored with care in accordance with the provisions of standard ISO 8828. The implants must be stored in their original sealed packaging.

Packaging and sterilization: The expiration date for sterilization must be checked. Only those products implanted before the end of the valid shelf-life may be considered sterile. The opening instructions are written on the packaging. Every precaution must be taken to ensure sterility when opening the packaging of the implant and when inserting it. Once the product packaging is opened or damaged, the product is no longer considered sterile. Inspect all packaging on arrival for evidence of shipping damage. Damaged packaging renders the product unsafe and it should not be used. Return all shipping damaged product promptly. Subsequently damaged product packaging requires product replacement. Product used in the operating room must be opened and placed into use using accepted operating room sterile technique.

Implant: The implants are supplied pre-sterilized (gamma radiation). The radiation dose selected is 2.5 M/rad minimum. The sterility Assurance Level (SAL) of the implants is at least 10^{-6}. The device may not be secondarily cleaned or resterilized.

Instrument: The recommended sterilization process for the graduated inserter is steam autoclave sterilization. The recommended sterilization cycle is based on AAMI guidelines. The cycle is saturated steam at 274° F for 18 minutes.

9) Applicant name & Address

Tornier S.A.
B.P. 11 - Rue Doyen Gosse
38330 Saint Ismier
France
Tel: 00 33 4 76 52 80 00
Fax: 00 33 4 76 52 80 36

10) Company contact

Tornier S.A.
Mrs Anne Le Rouzo
Regulatory affairs & Quality Manager
ZIRST - 161, rue Lavoisier
38330 Montbonnot
France
Tel: 00 33 4 76 61 35 00
Fax: 00 33 4 76 61 35 33

11) Submission correspondent

Mr David W. Schlerf
Buckman Company, Inc.
200, Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
Tel 925 356 2640
Fax 925 356 2654

12) Name and address of manufacturing/packaging/sterilization

Manufacturing/Packaging:

Tornier S.A.
Rue du Doyen Gosse
38330 Saint Ismier / France
Regulation number: 9610667

Sterilization :

IONISOS
Dagneux
01120 Montluel / France

GAMMASTER PROVENCE
M.I.N. 712
13323 Marseille Cedex 14 / France

CENG
17, avenue des Martyrs
38000 Grenoble / France

13) Comparison table

FEATURE	38 mm Tornier Cement Restrictor	24 mm Tornier Cement Restrictor	Allo Pro Obturator	SE ?
Indication for use	• Total Shoulder Arthroplasty • Total Hip Arthroplasty • Intramedulary Occlusion • Cement Pressurization	• Total Shoulder Arthroplasty • Total Hip Arthroplasty • Intramedulary Occlusion • Cement Pressurization	• Same • Hip only	Yes
Design	Daisy petal	Daisy petal	Ringed Cylindrical Plug	Yes/No
Sterility assurance level	10^{-6}	10^{-6}	10^{-6}	Yes
Sterilization method	Gamma - 2.5 M/rad min	Gamma - 2.5 M/rad min	Gamma - 2.5 M/rad min	Yes
Sizes	1	1	9	No
Material	UHMPE	UHMPE	UHMPE	Yes
Accessory items	Graduated inserter	Graduated inserter	Inserter, Vent tubing	Yes
Manufacturer	Tornier SA, France	Tornier SA, France	AlloPro, GmbH	Yes
Product code	87LZN	87LZN	87LZN	Yes
K-number	Pending	K973453	K830949	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2000

Mr. David Schlerf
Representing Tornier S.A.
Buckman Company
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523-3389

Re: K001932
Trade Name: Tornier Cement Restrictor
Regulatory Class: II
Product Code: JDI and LZN
Dated: June 13, 2000
Received: June 26, 2000

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Bochner.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001932

Device name: ***Tornier Cement Restrictor***

Indication for use:

1. **Total Shoulder Arthroplasty**
2. **Total Hip Arthroplasty**
3. **Intramedullary Occlusion**
4. **Cement Pressurization**

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER ~~PAGE IF NECESSARY~~

Concurrence of CDRH, Office of Device Evaluation ~~(ODE)~~

Donna R. Vochmen

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001932

Prescription use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109) (Optional format 1-2-96)